

Docket No.: CI-000

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Shirley I. MIEKKA et al.

Serial No.: 09/942,941

Filed: August 31, 2001

For: METHODS FOR STERILIZING  
PREPARATIONS CONTAINING  
ALBUMIN

:  
:  
: Group Art Unit: 2881  
:  
: Examiner:: Unassigned  
:  
:

RECEIVED  
APR 19 2002  
TECHNOLOGY CENTER 2800

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the indicated date. Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. §120. 1138 OG 37, 38 (May 19, 1992).

- X 1. This Information Disclosure Statement is being filed (i) within three months of the U.S. filing date of a U.S. application other than a CPA continued prosecution application under §1.53(d) OR (ii) within three months of the date of entry of the national stage as set forth in §1.491 in an international application OR (iii) before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 C.F.R. §1.97(b).
- 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application. 37 C.F.R. §1.97(c).
- a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- ☐ c. Attached is our check no. \_\_\_\_\_ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
- ☐ 3. This Information Disclosure Statement is being filed after the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application, but on or before payment of the Issue Fee. Attached is our check no. \_\_\_\_ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 C.F.R. §1.97(d).
- ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).
- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- ☒ 4. The relevancy of the non-English language references can be determined from the attached abstracts.
- ☒ 5. To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,  
FLESHNER & KIM, LLP



Mark L. Fleshner  
Registration No. 34,596  
Donald R. McPhail  
Registration No. 35,811

Correspondence Address:  
P.O. Box 221200  
Chantilly, VA 20153-1200  
Telephone: (703) 502-9440  
Date: April 18, 2002  
MLF:DRM:kpc

LIST OF PRIOR ART CITED BY  
APPLICANT

(PTO-1449)

ATTY. DOCKET NO.  
**CI-0003**APPLN. SERIAL NO.  
**09/942,941**APPLICANT  
**Shirley I. MIEKKA t al.**FILING DATE  
**August 31, 2001**GROUP  
**2881**

## U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
	RE 23,195	02/1950	Arno Brasch			
	2,832,689	04/1958	Bernard E. Proctor et al.			
	2,920,969	01/1960	E.S. Stoddard			
	2,962,380	11/1960	J.H. Wertheim			
	3,620,944	11/1971	Keiko Tanito			
	3,743,480	07/1973	John D. Falk			
	3,779,706	12/1973	Nablo			
	4,136,094	01/1979	Condie			
	4,251,437	02/1981	Rasmussen et al.			
	4,282,863	08/1981	Beigler et al.			
	4,330,626	05/1982	Blair et al.			

## U.S. PATENT APPLICATION PUBLICATIONS

	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	

## U.S. PATENT APPLICATIONS

	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	

## FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
	2,056,619	10/1991	Canada				
	310 316	04/1989	Europe (Abstract)			X	
	334 679	09/1989	Europe (Abstract)			X	
	919 918 A2	06/1999	Europe (Abstract)			X	
	919 918 A3	06/1999	Europe (Abstract)			X	

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)

	AABB FDA Liaison Meeting, ABC Newsletter, December 12, 1997, pp. 14
	Ozan Akkus et al., Fracture Resistance of Gamma Radiation Sterilized Cortical Bone Allografts, 2001, pps. 927-934, Journal of Orthopaedic Research, Vol. 19
	Tikvah Alper et al., The Exceptionally Small Size of the Scrapie Agent, 1966, pps. 278-284, Biochemical and Biophysical Research Communications, Vol. 22, No. 3

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

<b>LIST OF PRIOR ART CITED BY APPLICANT</b> (PTO-1449)				ATTY. DOCKET NO. <b>CI-0003</b>		APPLN. SERIAL NO. <b>09/942,941</b>	
				APPLICANT <b>Shirley I. MIEKKA et al.</b>			
				FILING DATE <b>August 31, 2001</b>		GROUP <b>2881</b>	

U.S. PATENT DOCUMENTS						
EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
	4,370,264	01/1983	Kotitschke et al.			
	4,409,105	10/1983	Hayashi et al.			
	4,472,840	09/1984	Jefferies			
	4,620,908	11/1986	Van Duzer			
	4,865,602	09/1989	Smestad et al.			
	4,933,145	06/1990	Uchida et al.			
	4,946,648	08/1990	Dichtelmüller et al.			
	4,963,356	10/1990	Calenoff et al.			
	5,000,951	03/1991	Bass et al.			
	5,106,619	04/1992	Wieschahn et al.			
	5,134,295	07/1992	Wälischmiller			
	5,185,371	02/1993	Rubinstein			

U.S. PATENT APPLICATION PUBLICATIONS						
EXAMINER'S INITIALS	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	FILING DATE

FOREIGN PATENT DOCUMENTS							
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
	11-216147	08/1999	Japan (Abstract)			X	
	1321420-A	07/1987	Soviet Union (Abstract)			X	
	WO 90/00907	02/1990	PCT Int'l (Abstract)			X	
	WO 91/16060	10/1991	PCT Int'l (Abstract)			X	
	WO 95/03071	02/1995	PCT Int'l (Abstract)			X	

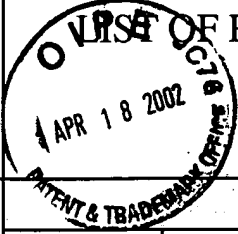
  

OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)	
	Tikvah Alper et al., Protection by Anoxia of the Scrapie Agent and Some DNA and RNA Viruses Irradiated as Dry Preparations, 1968, pps. 157-166, J. Gen. Virol., Vol. 3
	Tikvah Alper et al., Does the Agent of Scrapie Replicate Without Nucleic Acid? May 20, 1967, pps. 764-766, Nature, Vol. 214
	Tikvah Alper et al., The Scrapie Agent: Evidence Against its Dependence For Replication on Intrinsic Nucleic Acid, 1978, pps. 503-516, J. Gen. Virol., Vol. 41

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

				ATTY. DOCKET NO. <b>CI-0003</b>		APPLN. SERIAL NO. <b>09/942,941</b>	
				APPLICANT <b>Shirly I. MIEKKA et al.</b>			
				FILING DATE <b>August 31, 2001</b>		GROUP <b>2881</b>	
<b>U.S. PATENT DOCUMENTS</b>							
EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE	
	5,226,065	07/1993	Held et al.				
	5,362,442	11/1994	Kent				
	5,418,130	05/1995	Plat. et al.				
	5,460,962	10/1995	Kemp				
	5,510,122	04/1996	Sreebny et al.				
	5,603,894	02/1997	Aikus et al.				
	5,609,864	03/1997	Shanbrom				
	5,637,451	06/1997	Ben-Hur et al.				
	5,643,464	07/1997	Rhee et al.				
	5,712,086	01/1998	Horowitz et al.				
	5,730,933	03/1998	Peterson				
	5,817,528	10/1998	Böhm et al.				
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>							
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS		
<b>FOREIGN PATENT DOCUMENTS</b>							
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
	WO 00/25839	03/2000	PCT Int'l (Abstract)			X	
	WO 01/08611A1	02/2001	PCT Int'l (Abstract)			X	
	WO 01/12318A1	02/2001	PCT Int'l (Abstract)			X	
	WO 01/32107A2	05/2001	PCT Int'l (Abstract)			X	
	WO 01/32110A2	05/2001	PCT Int'l (Abstract)			X	
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>							
	S.R. Aparicio et al., Light and Electron Microscopy Studies on Homograft and Heterograft Heart Valves, 1975, pps. 174-162, J. Path, Vol. 115						
	J. Baksa et al., The Use of Pig's Skin (xenograft) for the Treatment of Burns, 1976, pps. 138-145, Magyar Traumatologin, Vol. 19						
	Michael L. Baldwin et al., Irradiation of Blood Components, 1992, pps. 10-78, American Association of Blood Banks						
EXAMINER				DATE CONSIDERED			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

<b>LIST OF PRIOR ART CITED BY APPLICANT</b> (PTO-1449)				ATTY. DOCKET NO. <b>CI-0003</b>		APPLN. SERIAL NO. <b>09/942,941</b>	
				APPLICANT <b>Shirley I. MIEKKA et al.</b>			
				FILING DATE <b>August 31, 2001</b>		GROUP <b>2881</b>	

U.S. PATENT DOCUMENTS						
EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
	5,837,313	11/1998	Ding et al.			
	5,881,534	03/1999	Ahlqvist et al.			
	5,981,163	11/1999	Horowitz et al.			
	5,986,168	11/1999	Noishiki			
	6,046,024	04/2000	Burton et al.			
	6,049,025	04/2000	Stone et al.			
	6,066,626	05/2000	Yew et al.			
	6,087,141	07/2000	Margolis-Nunno et al.			
	6,120,592	09/2000	Brault et al.			
	6,159,490	12/2000	Deghenghi			
	6,171,549	01/2001	Kent			

U.S. PATENT APPLICATION PUBLICATIONS						
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	

U.S. PATENT APPLICATIONS						
	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	

FOREIGN PATENT DOCUMENTS							
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
	WO 01/45720A1	06/2001	PCT Int'l (Abstract)			X	
	WO 01/49219A1	07/2001	PCT Int'l (Abstract)			X	
	WO 01/72233A1	10/2001	PCT Int'l (Abstract)			X	
	WO 01/72244A1	10/2001	PCT Int'l (Abstract)			X	
	WO 01/91818A1	12/2001	PCT Int'l (Abstract)			X	

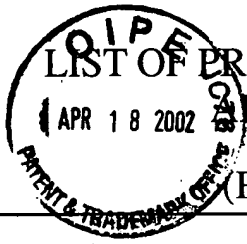
  

OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)	
	R.H. Bassin et al., Abrogation of Fv-1 <sup>b</sup> Restriction With Murine Leukemia Viruses Inactivated by Heat or by Gamma Irradiation, May 1978, pps. 306-315, Journal of Virology, Vol. 26, No. 2
	Guy Beauregard et al., Temperature Dependence of the Radiation Inactivation of Proteins, 1985, pps. 117-120, Analytical Biochemistry, Vol. 150
	Sandra Blakeslee, Tight Rules on Use of Organs Do Not Apply to Tissues, January 20, 2002, The New York Times Newspaper

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

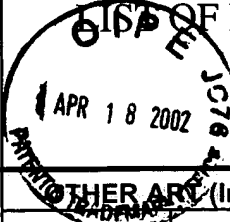
 <b>LIST OF PRIOR ART CITED BY APPLICANT</b> (PTO-1449)				ATTY. DOCKET NO. <b>CI-0003</b>		APPLN. SERIAL NO. <b>09/942,941</b>	
				APPLICANT <b>Shirley I. MIEKKA t al.</b>			
				FILING DATE <b>August 31, 2001</b>		GROUP <b>2881</b>	
<b>U.S. PATENT DOCUMENTS</b>							
EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE	
	6,187,572	02/2001	Platz et al.				
	6,190,855	02/2001	Herman et al.				
	6,197,207	03/2001	Chapman et al.				
	6,203,544	03/2001	Gotzen				
	6,214,534	04/2001	Horowitz et al.				
	6,235,508	05/2001	Sowemimo-Coker et al.				
	4,784,850	11/1998	Abraham				
	4,798,611	01/1989	Freeman, Jr.				
	5,283,034	02/1994	Okrongly et al.				
	5,548,066	08/1996	Leneau et al.				
	5,989,498	11/1999	Odland				
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>							
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS		
<b>U.S. PATENT APPLICATIONS</b>							
	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS		
<b>FOREIGN PATENT DOCUMENTS</b>							
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>							
	Seymour S. Block, Disinfection, Sterilization, and Preservation, Fundamental Principles of Activity Principles of Antimicrobial Activity, Fourth Edition, 1991, pps. 31-33						
	A.J.J.C. Bogers et al., Long-Term Results of the Gamma-Irradiation-Preserved Homograft Monocusp for Transannular Reconstruction of the Right-Ventricular Outflow Tract in Tetralogy of Fallot, 1994, pps. 337-330, Thorac. Cardiovasc. Surgeon, Vol. 42						
	David R. Brown et al., Antioxidant Activity Related to Copper Binding of Native Prion Protein, 2001 pps. 69-76, Journal of Neurochemistry, Vol. 76						
EXAMINER				DATE CONSIDERED			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

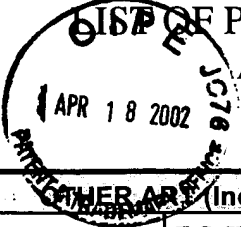
<p><b>LIST OF PRIOR ART CITED BY APPLICANT</b></p> <p>(PTO-1449)</p> <p><b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b></p>	ATTY. DOCKET NO. <b>CI-0003</b>	APPLN. SERIAL NO. <b>09/942,941</b>		
	APPLICANT <b>Shirly I. MIEKKA t al.</b>			
	FILING DATE <b>August 31, 2001</b>	GROUP <b>2881</b>		
<p>P. Brown, The Risk of Blood-Borne Creutzfeldt-Jakob Disease, 1999, pps. 53-59, Advances in Transfusion Safety Dev. Biol. Vol. 102</p> <p>P. Brown et al., Further Studies of Blood Infectivity in an Experimental Model of Transmissible Spongiform Encephalopathy, With an Explanation of Why Blood Components Do Not Transmit Creutzfeldt-Jakob Disease in Humans, November/December 1999, pps. 1169-1178, Transfusion, Vol. 39</p> <p>Paul Brown et al., Effect of Chemicals, Heat, and Histopathologic Processing on High-Infectivity Hamster-Adapted Scrapie Virus, May 1982, pps. 683-687, The Journal of Infectious Diseases, Vol. 145, No. 5</p> <p>P. Brown et al., The Distribution of Infectivity in Blood Components and Plasma Derivatives in Experimental Models of Transmissible Spongiform Encephalopathy, September 1998, pps. 810-816, Transfusion, Vol. 38</p> <p>D.G. Campbell et al., Sterilization of HIV With Irradiation: Relevance to Infected Bone Allografts, 1999, pps. 517-521, Aust. N.Z.J. Surg., Vol. 69</p> <p>Ernest U. Conrad et al., Transmission of the Hepatitis-C Virus by Tissue Transplantation, February 1995, pps. 214-224, The Journal of Bone and Joint Surgery, Vol. 77-A, No. 2</p> <p>A.S. Dagli, Correction of Saddle Nose Deformities by Coral Implantation, 1997, pps. 274-276, Eur. Arch. Otorhinolaryngol, Vol. 254</p> <p>Defeng et al., Sterilization of Silver-Acidum Pipemedicum Skin for the Treatment of Burns by Radioactive Cobalt-60-Gamma-Ray, 1995, pps. 406 (Abstract)</p> <p>P. Di Simplicio et al., The Reactivity of the SH Group of Bovine Serum Albumin With Free Radicals, 1991, pps. 253-262, Free Rad. Res. Comms., Vol. 14, No. 4</p> <p>R.J. Donnelly et al., Gamma-radiation of Heart Valves at 4°C; A Comparative Study Using Techniques of Histochemistry and Electron and Light Microscopy, 1973, pps. 95-101, Thorax, Vol. 28</p> <p>Duane C. Eichler et al., Radiation Inactivation Analysis of Enzymes, July 15, 1987, pps. 9433-9436, The Journal of Biological Chemistry, Vol. 262, No. 20</p> <p>Luanne H. Elliott et al., Inactivation of Lassa, Marburg and Ebola Viruses by Gamma Irradiation, Oct. 1982, pps. 704-708, Journal of Clinical Microbiology, Vol. 16, No. 4</p> <p>Bradley M. Fideler et al., Gamma Irradiation: Effects on Biomechanical Properties of Human Bone-Patellar Tendon-Bone Allografts, 1995, pps. 643-646, American Journal of Sports Medicine, Vol. 23, No. 5</p> <p>Bradley M. Fideler et al., Effects of Gamma Irradiation on the Human Immunodeficiency Virus, July 1994, The Journal of Bone and Joint Surgery, Vol. 76-A, No. 7</p> <p>Fields et al., Susceptibility of Scrapie Agent to Ionizing Radiation, April 5, 1969, pps. 90-91, Nature, Vol. 222</p> <p>M.J. Gibbons et al., Effects of Gamma Irradiation on the Initial Mechanical and Material Properties of Goat Bone-Patellar Tendon-Bone Allografts, 1991, pps. 209-218, J. Orthop Res, Vol. 9, No. 2</p>	<table border="1"> <tr> <td data-bbox="852 1638 1177 1707"><b>EXAMINER</b></td> <td data-bbox="1177 1638 1479 1707"><b>DATE CONSIDERED</b></td> </tr> </table>		<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
<b>EXAMINER</b>	<b>DATE CONSIDERED</b>			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

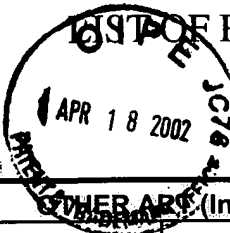


 <p><b>LIST OF PRIOR ART CITED BY APPLICANT</b> (PTO-1449)</p>	ATTY. DOCKET NO. <b>CI-0003</b>	APPLN. SERIAL NO. <b>09/942,941</b>
	APPLICANT <b>Shirley I. MIEKKA et al.</b>	
	FILING DATE <b>August 31, 2001</b>	GROUP <b>2881</b>
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>		
J.R.P. Gibbons et al., Gamma Ray Sterilisation of Homograft Valves, 1969, pps. 353-358, Bulletin De La Societe Internationale De Chirurgie, No. 3		
M.J. Goertzen et al., Anterior Cruciate Ligament Reconstruction Using Cryopreserved Irradiated Bone-ACL-Bone-Allograft Transplants, 1994, pps. 150-157, Knee Surgery Sports Traumatology Arthroscopy, Vol. 2		
M.J. Goertzen et al., Sterilisation of Canine Anterior Cruciate Allografts by Gamma Irradiation in Argon, March 1995, pps. 205-212, The Journal of Bone and Joint Surgery, Vol. 77-B, No. 2		
Slawomir Gregorczyk et al., Strength of Lyophilized and Irradiated Cortical Bone of the Human Femur, 1995, pps. 129-133, Chir. Narz. Ruchu Ortop. Pol., Lx 2		
D.A. Haig, Further Studies on the Inactivation of the Scrapie Agent by Ultraviolet Light, 1969, pps. 455-457, J. Gen. Virol., Vol. 5		
F.W. Hehrlein et al., Biochemische Veränderungen an Heterologen Aortenklappentransplantaten nach Anwendung Verschiedener Sterilisationsverfahren, pps. 1183-1185, Langenbecks Arch. Chir., Bd. 325 (Kongreßbericht) (English Summary found at page 1183)		
F.W. Hehrlein et al., Morphologische Untersuchungen an Heterologen Herzklappentransplantaten Unter Verschiedenen Sterilisationsbedingungen, pps. 244-251 (English Summary found at page 250)		
H. Hiemstra et al., Inactivation of Human Immunodeficiency Virus by Gamma Radiation and its Effect on Plasma and Coagulation Factors, 1991, pps. 32-39, Transfusion, Vol. 31, No. 1		
Richard Hinton et al., A Biomechanical Analysis of Solvent-dehydrated and Freeze-Dried Human Fascia Lata Allografts, 1992, pps. 607-612, The American Journal of Sports Medicine, Vol. 20, No. 5		
B. Horowitz et al., Inactivation of Viruses in Labile Blood Derivatives, II. Physical Methods, 1985, pps. 523-527, Transfusion, Vol. 25, No. 6		
M. Horowitz, Sterilization of Homograft Ossicles by Gamma Radiation, November 1979, pps. 1087-1089, The Journal of Laryngology and Otology, Vol. 93		
Carol House et al., Inactivation of Viral Agents in Bovine Serum by Gamma Irradiation, 1990 pps. 737-740, Can. J. Microbiol., Vol. 36		
Shinichiro Ijiri et al., Effect of Sterilization on Bone Morphogenetic Protein, 1994, pps. 628-636, Journal of Orthopaedic Research, Vol. 12		
A.S. Imamaliyev et al., Biological Properties of Bone Tissue Conserved in Plastic Material and Sterilized With Gamma Rays, 1974, pps. 129-135, ACTA, Chirurgiae Plasticae, Vol. 16, No. 3		
A. Ingegneri et al., An 11-Year Assessment of 93 Flash-frozen Homograft Valves in the Aortic Position, 1979, pps. 304-307, Thorac. Cardiovasc. Surgeon, Vol. 27		
J. Jerosch et al., A New Technique for Bone Sterilization, 1989, pps. 117-120, Biomedizinische Technik, Band 34, Heft 5		
J. Jerosch et al., Influence of Different Rehydration Periods on the Stability and the Water Content of Bone Allografts After Lyophilization, Gamma-Irradiation, and Lipid Extraction, 1994, pps. 335-341, Z. Orthop., Vol. 132		
J.D. Keathley et al., Is There Life After Irradiation? Part 2: Gamma-Irradiated FBS in Cell Culture July/August 1993, pps. 46-52, BioPharm		
<b>EXAMINER</b>	<b>DATE CONSIDERED</b>	

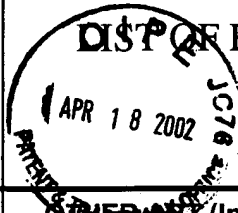
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

<div style="text-align: center;">  <p><b>6157 OF PRIOR ART CITED BY APPLICANT</b> (PTO-1449)</p> </div>	ATTY. DOCKET NO. <b>CI-0003</b>	APPLN. SERIAL NO. <b>09/942,941</b>
	APPLICANT <b>Shirly I. MIEKKA t al.</b>	
	FILING DATE <b>August 31, 2001</b>	GROUP <b>2881</b>
<b>OTHER ARTS (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>		
	E.S. Kempner et al., Size Determination of Enzymes by Radiation Inactivation, 1979, pps. 2-10, Analytical Biochemistry, Vol. 92	
	L. Kerboull et al., In Vitro Study of the Influence of Various Conservation Methods on the Mechanical Properties of Patellar Tendon Allografts, 1991, pps. 751-762, Chirurgie, Vol. 117	
	A.D. Kitchen, Effect of Gamma Irradiation on the Human Immunodeficiency Virus and Human Coagulation Proteins, 1989, pps. 223-229, Vox Sang, Vol. 56	
	Andrezej Komender et al., Some Biological Properties of Bovine Trypsinized Fascia Xenografts, 1981, pps. 485-489, Archivum Immunologiae et Therapiae Experimentalis, Vol. 29	
	Andrezej Komendar et al., Some Biological Properties of Preserved Bovine Fascia Enriched With Pulverized Calf Cartilage, 1984, pps. 211-219, Archivum Immunologiae et Therapiae Experimentalis, Vol. 32	
	J.F. Kouvalchouk et al., The Use of Sterilized Bone Allografts in Reconstruction After Tumour Resection, 1986, pps. 393-401, Revue de Chirurgie Orthopedique, Vol. 72	
	Raymond Latarjet, Inactivation of the Agents of Scrapie, Creutzfeldt-Jakob Disease, and Kuru by Radiations, 1979, pps. 387-407, Slow Transmissible Diseases of the Nervous System, Vol. 2	
	R. Latarjet et al., Inactivation of the Scrapie Agent by Near Monochromatic Ultraviolet Light, September 26, 1970, pps. 1341-1343, Nature, Vol. 227	
	Douglas C. Lee et al., A Direct Relationship Between the Partitioning of the Pathogenic Prion Protein and Transmissible Spongiform Encephalopathy Infectivity During the Purification of Plasma Proteins, April 2001, pps. 449-455, Transfusion, Vol. 41	
	Susan F. Leitman, Use of Blood Cell Irradiation in the Prevention of Posttransfusion Graft-vs-Host Disease, 1989, pps. 219-232, Transfus. Sci., Vol. 10	
	Linberg et al., Irradiated Homologous Cartilage For Orbital Reconstruction, July 1980, pps. 457-462, Ophthalmic Surgery, Vol. 11	
	Sandra McDowell, Irradiated Cartilage, Spring 1988, pps. 14-15, Plastic Surgical Nursing	
	A. Maeda et al., Effects of Solvent Preservation With or Without Gamma Irradiation on the Material Properties of Canine Tendon Allografts, 1993, pps. 181-189, Journal of Orthopaedic Research, Vol. 11	
	Akira Maeda et al., Solvent-dried and Gamma-irradiated Tendon Allografts in Rats, July 1998, pps. 731-736, The Journal of Bone and Joint Surgery, Vol. 80-B, No. 4	
	S. Malawski et al., The Use of Dry-Frozen Bone Grafts Sterilized by Gamma Rays in Orthopaedic Surgery, 1969, pps. 61-68, Chir. Narz. Ruchu Ortop.	
	Linda Marton et al., Disinfection and Inactivation of the Human T. Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus, August 1985, pps. 499-503, The Journal of Infectious Diseases, Vol. 151, No. 2	
	S.I. Miekka et al., New Methods for Inactivation of Lipid-enveloped and Non-enveloped Viruses, 1998, pps. 402-408, Haemophilia, Vol. 4	
	Ken Nakata et al., Reconstruction of the Lateral Ligaments of the Ankle Using Solvent-dried and Gamma-Irradiated Allogeneic Fascia Lata, May 2000, pps. 579-582	
	Maria Esther Martinez Pardo et al., Clinical Application of Amniotic Membranes on a Patient With Epidermolysis Bullosa, 1999, pps. 68-73, Annals of Transplantation, Vol. 4, No. 3-4	
<b>EXAMINER</b>	<b>DATE CONSIDERED</b>	


EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

<div style="text-align: center;">  <p><b>OFFICE OF PRIOR ART CITED BY APPLICANT</b> (PTO-1449)</p> </div>	<b>ATTY. DOCKET NO.</b> <b>CI-0003</b>	<b>APPLN. SERIAL NO.</b> <b>09/942,941</b>
	<b>APPLICANT</b> <b>Shirley I. MIEKKA t al.</b>	
	<b>FILING DATE</b> <b>August 31, 2001</b>	<b>GROUP</b> <b>2881</b>
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>		
Jan Parizek et al., Duraplasty With Pretreated Freeze-Dried Sterilized Human Dura Mater, 1990, pps. 135-143, Sbor. ved. Praci LF UK Hradee Kralove, Vol. 33		
Jan Parizek et al., Ovine Pericardium: A New Material For Duraplasty, 1996, pps. 508-513, J. Neurosurg., Vol. 84		
Patel et al., Effect of Gamma Radiation and Ethylene Oxide on Papain, 1979, pps. 81-83, Indian. J. Pharm. Sci., Vol. 41, No. 2		
L.V. Polezhau et al., Repair of Cranial Defects With Regenerating Bone in Grafting Gamma-Irradiated Bone Filings, pps. 57-60		
Pollard, The Effect of Ionizing Radiation on Viruses, pps. 65-71		
Donald J. Prolo et al., Composite Autogeneic Human Cranioplasty: Frozen Skull Supplemental With Fresh Iliac Corticocancellous Bone, December 1984, pps. 846-851, Neurosurgery, Vol. 15, No. 6		
Donald J. Prolo et al., Superior Osteogenesis in Transplanted Allogeneic Canine Skull Following Chemical Sterilization, August 1982, pps. 230-242, Clinical Orthopaedics and Related Research, No. 168		
Elena Quaglio et al., Copper Converts the Cellular Prion Protein Into a Protease-resistant Species That Is Distinct From the Scrapie Isoform, April 6, 2001, pps. 11432-11438, The Journal of Biological Chemistry, Vol. 276, No. 14		
T.J. Rasmussen et al., The Effects of 4 Mrad of Gamma-Irradiation on the Initial Mechanical Properties of Bone-Patellar Tendon-Bone Grafts, 1994, pps. 188-197, The Journal of Arthroscopic and Related Surgery, Vol. 10, No. 2		
Brian D. Reid, The Sterways Process: A New Approach to Inactivating Viruses Using Gamma Radiation, 1998, pps. 125-130, Biologicals, Vol. 26		
S.C. Roe et al., The Effect of Gamma Irradiation on a Xenograft Tendon Bioprosthesis, 1992, pps. 149-154, Clinical Materials, Vol. 9		
Robert G. Rohwer, Estimation of Scrapie Nucleic Acid MW From Standard Curves for Virus Sensitivity to Ionizing Radiation, March 27, 1986, pp. 381, Nature, Vol. 320, No. 6060		
Robert G. Rohwer, Scrapie Infectious Agent is Virus-like in Size and Susceptibility to Inactivation, April 12, 1984, pps. 658-662, Nature, Vol. 308		
R.G. Rohwer, The Scrapie Agent: A Virus by Any Other Name, pps. 195-232, Current Topics in Microbiology and Immunology, Vol. 172		
Robert G. Rohwer et al., Scrapie-Virus or Viroid, The Case For A Virus, pps. 333-355, Laboratory of Central Nervous System Studies, National Institutes of Neurological and Communicative Disorders and Stroke, National Institutes of Health		
Robert G. Rohwer, Virus-Like Sensitivity of the Scrapie Agent to Heat Inactivation, February 10, 1984, pps. 600-602, Science, Vol. 223		
<b>EXAMINER</b>	<b>DATE CONSIDERED</b>	

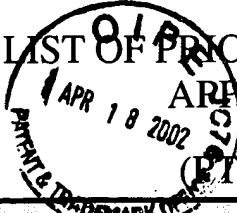
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

	ATTY. DOCKET NO. <b>CI-0003</b>	APPLN. SERIAL NO. <b>09/942,941</b>
	APPLICANT <b>Shirly I. MIEKKA t al.</b>	
	FILING DATE <b>August 31, 2001</b>	GROUP <b>2881</b>
<b>REFERENCES (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>		
	Robert Sullivan et al., Inactivation of Thirty Viruses by Gamma Radiation, July 1971, pps. 61-65, Applied Microbiology, Vol. 22, No. 1	
	D. Tylman, Mechanical Character of Liofilized and Sterilized by Gamma-Rays Bone Tissue, 1996, pps. 229-234, Chirurgia Narzadow Ruchu I, Ortopedia Polska	
	W. Welch, A Comparative Study of Different Methods of Processing Aortic Homografts, 1969, pps. 746-749, Thorax, Vol. 24	
	J.M. White et al., Sterilization of Teeth by Gamma Radiation, September 1994, pps. 1560-1567, J. Dent. Res., Vol. 73, No. 9	
	Boon-Seng Wong et al., Copper Refolding of Prior Protein, 2000, pps. 1217-1224, Biochemical and Biophysical Research Communications, Vol. 276	
	Boon-Seng Wong et al., Differential Contribution of Superoxide Dismutase Activity by Prior Protein in Vivo, 2000, pps. 136-139, Biochemical and Biophysical Research Communications, Vol. 273	
	Boon-Seng Wong et al., Prion Disease: A Loss of Antioxidant Function? 2000, pps. 249-252, Biochemical and Biophysical Research Communications, Vol. 275	
	D.E. Wyatt et al., Is There Life After Irradiation? Part I: Inactivation of Biological Contaminants, June 1993, pps. 34-39, BioPharm	
	Qi Zhang et al., Ethylene Oxide Does Not Extinguish the Osteoinductive Capacity of Demineralized Bone, 1997, pps. 104-108, Acta Orthop Scand, Vol. 68, No. 2	
	Yongxing Zhang et al., A Comprehensive Study of Physical Parameters, Biomechanical Properties and Statistical Correlations of Iliac Crest Bone Wedges Used in Spinal Fusion Surgery, 1994, pps. 304-308, Spine, Vol. 19, No. 3	
	License Amendment and procedures for Gamma Irradiation of Blood Products, June 22, 1993, pps. 1-18, Dept. of Health & Human Services, Food and Drug Administration	
	M.F. Alladine et al., $\gamma$ -Radiation Damage to Starr-Edwards Valves, March 16, 1998, pp. 68, The Lancet, Letters to the Editor	
	Ch. Baquay et al., Radiosterilization of Albuminated Polyester Prostheses, May 1987, pps. 185-189, Biomaterials, Vol. 8	
	Edward H. Bedrossian, Jr., HIV and Banked Fascia Lata, 1991, pps. 284-288, Ophthalmic Plastic and Reconstructive Surgery, Vol. 7, No. 4	
	Liu Bingci, Mouse Antibody Response Following Repetitive Injections of Gamma-Irradiated Human Placenta Collagen, June 1994, pps. 100-103, Chinese Medical Sciences Journal, Vol. 9, No 2	
	A.A. Belov et al., The Influence of $\gamma$ -Radiation on Enzyme Activity of Collalitin in the Process of Storage, 12/07/89, pps. 519-521, All-Union Research Institute of Textile and Haberdashery Industry, Moscow	
	R.G. Burwell, The Fate of Freeze-Dried Bone Allografts, June 1976, pps. 95-111, Transplantation Proceedings, Vol. VII, No. 2, Supplement 1	
<b>EXAMINER</b>	<b>DATE CONSIDERED</b>	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

<div style="text-align: center;">  <p><b>LIST OF PRIOR ART CITED BY APPLICANT</b> (PTO-1449)</p> </div>	ATTY. DOCKET NO. <b>CI-0003</b>	APPLN. SERIAL NO. <b>09/942,941</b>
	APPLICANT <b>Shirley I. MIEKKA t al.</b>	
	FILING DATE <b>August 31, 2001</b>	GROUP <b>2881</b>
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>		
	L. Callegaro et al., Hollow Fiber Immobilized L-Asparaginase: In Vivo and In Vitro Immunological Studies, 1983, pps. 91-96, The International Journal of Artificial Organs, Vol. 6, No. 2	
	G. Campalani et al., Aortic Valve Replacement With Frozen Irradiated Homografts, 1989, pps. 558-561, Eur. J. Cardio-thoracic Surgery, Vol. 3	
	David T. Cheung et al., The Effect of $\gamma$ -Irradiation on Collagen Molecules, Isolated $\alpha$ -chains, and Crosslinked Native Fibers, 1990, pps. 581-589, Journal of Biomedical Materials Research, Vol. 24	
	David J. Cohen et al., The Fate of Aortic Valve Homografts 12 to 17 Years After Implantation, March 1988, pps. 482-484, Chest, Vol. 93, No. 3	
	A.G. Churchalin et al., Clinical Immunosorbents Basing On Space-Network Polymers, 1998, pps. 1524-1529, All Union Research Institute of Chemical Reagents and Chemicals of Special Purity, Moscow	
	P. De Deyne et al., Some Effects of Gamma Irradiation on Patellar Tendon Allografts, 1991, pps. 51-62, Connective Tissue Research, Vol. 27	
	R.I. Vaida et al., Structural-Functional Peculiarities of Myocardial Capillaries After Resection of the Lungs, 10/21/86, pps. 68-73	
	R. Guidoin et al., A Compound Arterial Prosthesis: The Importance of the Sterilization Procedure on the Healing and Stability of Albuminated Polyester Grafts, March 1985, pps. 122-128, Biomaterials, Vol. 6	
	Ph. Hernigou et al., Radiation Sterilization of Bone and the HIV Virus, 1993, pps. 445-451, Revue de Chirurgie Orthopedique, Vol. 79	
	Hsing-Wen Sung et al., Effects of Various Chemical Sterilization Methods on the Crosslinking and Enzymatic Degradation Characteristics of an Epoxy-Fixed Biological Tissue, December 1996, pps. 376-383, Sterilization of Biological Tissues	
	James R. Malm et al., An Evaluation of Aortic Valve Homografts Sterilized by Electron Beam Energy, October 1967, pps. 471-477, Journal of Thoracic and Cardiovascular Surgery, Vol. 54, No. 4	
	James R. Malm et al., Results of Aortic Valve Replacement Utilizing Irradiated Valve Homografts, pps. 740-747, Annals New York Academy of Sciences	
	W. Oh et al., Mitral Valve Replacement With Preserved Cadaveric Aortic Homografts, May 1973, pps. 712-721, The Journal of Thoracic and Cardiovascular Surgery, Vol. 65, No. 5	
	K. Pietrucha, New Collagen Implant As Dural Substitute, April 1991, pps. 320-323, Biomaterials, Vol. 12	
<b>EXAMINER</b>	<b>DATE CONSIDERED</b>	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

<div style="text-align: center;">  <p><b>LIST OF PRIOR ART CITED BY APPLICANT</b> (PTO-1449)</p> </div>	ATTY. DOCKET NO. <b>CI-0003</b>	APPLN. SERIAL NO. <b>09/942,941</b>
	APPLICANT <b>Shirly I. MIEKKA et al.</b>	
	FILING DATE <b>August 31, 2001</b>	GROUP <b>2881</b>
<b>OTHER ART (including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>		
	Maria Raptopoulou-Gigi et al., Antimicrobial Proteins in Sterilised Human Milk, January 1, 1977, pps. 12-14, British Medical Journal, Vol. 1	
	Edward A. Rittenhouse et al., Sterilization of Aortic Valve Grafts for Transplantation, July 1970, pps. 1-5, Aortic Valve Grafts for Transplantation, Archives of Surgery, Vol. 101, No. 1	
	H. Sato et al., Sterilization of Therapeutic Immunoabsorbents by Ionizing Radiation, 1986, pps. 131-136, The International Journal of Artificial Organs, Vol. 9, No. 2	
	Richard A. Smith et al., Gamma Irradiation of HIV-1, 2001, pps. 815-819, Journal of Orthopaedic Research, Vol. 19	
	Barbara Lüssi-Schlatter et al., Die Antimikrobielle Behandlung von Peroralen Enzympräparaten mit Gamma-Strahlen, Pharmazeutisches Institut der Eidgenössischen Technischen Hochschule Zürich Galenische Abteilung	
	Martindale's Extra Pharmacopoeia, Glucose p. 1265; prior art The Merck Index, Eleventh Edition Glucose pp. 4353-4354, prior art	
	G.L. Moore et al., Effects of 4000 Rad. Irradiation on the In Vitro Storage Properties of packed Red Cells, Nov-Dec 1985, pps. 583-585, Final Rept., Pub. In Transfusion, Vol. 25, No 6 (Abstract)	
	Shcheglova et al., The Effect of the Power of Gamma-Radiation on the Radiation Dose in the Sterilization of Drugs, 1984, pps. 730-732, Khim-Farm Zh, Vol. 18, No. 6 (Abstract)	
	G.A. Yarygina, Dose Rate Effect on Survival of Microorganisms Used As Test-Cultures in Radiation Sterilization of Medical Products, 1973, pps. 32-39, Radiats. Tekh., No. 9 (Abstract)	
	O. Cornu et al., Effect of Freeze-Drying and Gamma Irradiation on the Mechanical Properties of Human Cancellous Bone, 2000, pps. 426-431, Journal of Orthopaedic Research, Vol. 18	
	Anna Dziedzic-Goclawska et al., Effect of Radiation Sterilization on the Osteoinductive Properties and the Rate of Remodeling of Bone Implants Preserved by Lyophilization and Deep-Freezing, November 1991, pps. 30-37, Clinical Orthopaedics and Related Research, Vol. 272	
	Ole T. Jensen et al., Vertical Guided Bone-Graft Augmentation in a New Canine Mandibular Model, November 3, 1995, pps. 335-343, The International Journal of Oral and Maxillofacial Implants, Vol. 10	
	Ronald W. Katz et al., Radiation-Sterilized Insoluble Collagenous Bone Matrix is a Functional Carrier of Osteogenin for Bone Induction, 1990, pps. 183-185, Calcified Tissue International, Vol. 47	
	Everard Munting et al., Effect of Sterilization on Osteoinduction, 1988, pps. 34-38, Acta Orthop Scand, Vol. 59, No. 1	
	P.A. Puolakkainen et al., The effect of Sterilization on Transforming Growth Factor $\beta$ Isolated From Demineralized Human Bone, 1993, pps. 679-685, Transfusion, Vol. 33, No 8	
	U. Ripamonti et al., Long-Term Evaluation of Bone Formation by Osteogenic Protein 1 in the Baboon and Relative Efficacy of Bone-Derived Bone Morphogenetic Proteins Delivered by irradiated Xenogeneic Collagenous Matrices, 2000, pps. 1798-1809, Journal of Bone and Mineral Research, Vol. 15, No. 9	
<b>EXAMINER</b>	<b>DATE CONSIDERED</b>	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

[illegible]

**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.